



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

**Government-owned Inventions; Availability for Licensing and
Collaboration; Notification of Q&A Webinar**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The invention named in this notice is owned by agencies of the United States Government and is available for licensing in accordance with the US Federal Technology Transfer Act of 1986. Related data for 510(k) submission is available as part of the licensing package. The technology and related data are being licensed to achieve expeditious commercialization of federally funded research and development. A U.S. Provisional patent application has been filed to extend market coverage. CDC also seeks collaboration partners with interest in adapting the test for different equipment, point-of-care, or more rapid

processing.

DATES: Individuals interested in this technology opportunity are invited to participate in a live question and answer webinar on April 27, 2018 at 10 A.M. Eastern Daylight Time.

ADDRESSES: Licensing, related data for 510(k) submission, and other information pertaining to the technology listed below, may be obtained by writing to Technology Transfer Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop D-42, Atlanta, GA 30329; Telephone (404)639-1330; or email tto@cdc.gov.

SUPPLEMENTARY INFORMATION:

Description of Technology:

CDC Trioplex Real-time RT-PCR (Reverse Transcription Polymerase Chain Reaction) Assay for Detection of Zika, Dengue, & Chikungunya Virus Infections

CDC ref. no.: I-009-17

NIH ref. no.: E-081-2017 (See

<https://www.ott.nih.gov/technology/e-081-2017.>)

CDC has developed the Trioplex real-time RT-PCR test to detect evidence of Zika, dengue and chikungunya virus infections, all of which are spread by mosquito bites from the same *Aedes* species and cause epidemics in more than 100 countries. The real-time RT-PCR assay is for qualitative detection and differentiation of RNA (ribonucleic acid) from dengue, chikungunya, and Zika viruses in serum, whole blood, and cerebral spinal fluid, and for the qualitative detection of Zika virus RNA in urine and amniotic fluid. This assay protocol is designed to facilitate simultaneous testing for the three viruses using a single sample in the same plate well (multiplex). A singleplex reaction (measuring one analyte at a time) is also an option for chikungunya, and dengue testing if one primer/probe set per well is preferred. The test can be run in different modalities and equipment available in most laboratories. The test has been designed to minimize the likelihood of false positive results. Cross-reactivity for any of the components is not expected. The Food & Drug Administration (FDA) issued emergency use authorization (EUA) for the Trioplex assay on March 17, 2016. Additional information can be found at:

<http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM491592.pdf>.

Currently, there are no vaccines or therapeutics commercially available for Zika, dengue, or chikungunya virus infections.

Competitive advantages:

- Currently, there is no multiplex assay on the market that can detect Zika, chikungunya and the four dengue subtypes in one test; this test will also help assess disease severity in dengue secondary infections
- There is no FDA-approved chikungunya PCR test on the market and current Zika and dengue tests must be run separately
- This was the first molecular test for Zika to receive FDA's EUA

Question and Answer Webinar:

Individuals interested in this technology opportunity are invited to participate in a live question and answer webinar on April 27, 2018 at 10 A.M. Eastern Daylight Time. Individuals must pre-register for the session by

sending an email to tto@cdc.gov by Thursday, April 26, at 1 PM EDT.

After requesting the registration, participants will receive a confirmation of their registration along with access information to enter prior to the webinar. Persons interested in this technology are strongly encouraged to register for and participate in the webinar.

A signed Confidential Disclosure Agreement (available under Forms at www.cdc.gov/tto) will be required to receive copies of unpublished patent applications and other information.

Inventors: Jorge Munoz-Jordan, Robert Lanciotti, and Gilberto Santiago.

U.S. PCT (Patent Cooperation Treaty) Application No.

PCT/US2017/023021: Filed March 17, 2017.

(CDC Ref. #: I-009-17; NIH Ref. #E-081-2017 - See <https://www.ott.nih.gov/technology/e-081-2017>.)

Dated: March 26, 2018.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

[FR Doc. 2018-06306 Filed: 3/28/2018 8:45 am; Publication Date: 3/29/2018]